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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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ADVISORY ACTION

Continuation of 3.

The proposed amendment, amending "w/w%" to "w/v%" in claims 1 and 16, would require new consideration and/or search and raise the issue of new matter because the amendment changes the range of concentrations for the instantly claimed composition. The proposed amendment would require new consideration of the composition based on this amended concentration and would raise the issue of new matter to determine if the amended concentration is supported in the specification as filed.

Continuation of 11.

Applicant's Remarks, filed 08 Aug 2008, have been fully considered and found not to be persuasive.

Regarding the rejection of claims 1-6, 8 ,10-13, 16 and 17 under 35 USC 102(b) as being anticipated by Harada et al., Applicants remark that the explicitly disclosed composition, referred to as "B solution", is in saline without any buffer. However, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art. See MPEP 2123. Harada et al. discloses a liquid preparation comprising the camptothecin analog T-0128 and an acetate buffer, reduced glutathione, EDTA, and Triton X-100, which are stabilizers or fillers, adjusted to pH 7 using acetate or phosphate buffers, optionally with $CaCl_2$, an alkaline earth metal chloride, added (page 402, right column, section 2.4. *In vitro evaluation of drug release*) in addition to the camptothecin analog T-0128 in the concentration of the "B solution" (page 403, left column, lines 22-23). One of skill in the art would instantly envision said

liquid preparation comprising a buffer at the concentration of the “B solution”. Therefore the analysis of Harada et al. in rejection of claims 1-6, 8 ,10-13, 16 and 17 under 35 USC 102(b) as anticipated is found to be proper.

Regarding the rejection of claims 1, 9 and 14-19 under 35 USC 103(a) as being unpatentable over Harada et al. in view of Wall et al., Applicants remark that the prior art does not teach stabilization of the camptothecin analog of the instant invention by lyophilization. In response to applicant's argument that the prior art does not teach the advantage of stabilization in the instant invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). As recited in the Office Action mailed 11 Feb 2008, one of ordinary skill in the art at the time of the invention would be motivated to combine the references because Wall et al. teaches the need for additional water-soluble camptothecin analogs (column 2 lines 2-5). With regard to the structural similarity of the camptothecin analogs, Wall et al. teaches a water-soluble camptothecin analog bound by amino acids to a macromolecule, a peptide, where as Harada et al. teaches a water-soluble camptothecin analog bound by amino acids to a carboxymethyl dextran, a macromolecule.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623